



DEPARTMENT OF VETERANS AFFAIRS

8320-01

38 CFR Part 17

RIN 2900-AP09

Health Care for Certain Children of Vietnam Veterans and Certain Korea Veterans –
Covered Birth Defects and Spina Bifida

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: This rule adopts as final a proposed rule of the Department of Veterans Affairs (VA) to amend its regulations concerning the provision of health care to birth children of Vietnam veterans and veterans of covered service in Korea diagnosed with spina bifida, except for spina bifida occulta, and certain other birth defects. In the proposed rule published on May 15, 2015, VA proposed changes to more clearly define the types of health care VA provides, including day health care and health-related services, which we defined as homemaker or home health aide services that provide assistance with Activities of Daily Living or Instrumental Activities of Daily Living that have therapeutic value. We also proposed changes to the list of health care services that require preauthorization by VA. This final rule addresses comments received from the public and adopts as final the proposed rule, without change.

DATES: Effective Date: This rule is effective on [insert date 30 days after date of publication in the FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Karyn Barrett, Director, Program Administration Directorate, Chief Business Office Purchased Care (10NB3), Veterans Health Administration, Department of Veterans Affairs, 810 Vermont Ave., NW., Washington, DC 20420, (303) 331-7500. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: Chapter 18 of title 38, United States Code, provides for benefits for certain birth children of Vietnam veterans and veterans of covered service in Korea who have been diagnosed with spina bifida, except spina bifida occulta, and certain other birth defects. These benefits include: (1) monthly monetary allowances for various disability levels; (2) health care; and (3) vocational training and rehabilitation. VA's regulations concerning health care for children authorized under this chapter are published at 38 CFR 17.900 through 17.905.

On May 15, 2015, VA published a proposed rule to more clearly define the types of healthcare VA provides, including day healthcare and health-related services, which VA would define as homemaker or home health aide services that provide assistance with Activities of Daily Living or Instrumental Activities of Daily Living that have therapeutic value; and to make changes to the list of health care services that require preauthorization by VA. (80 FR 27878). The comment period closed on June 14, 2015. We received ten comments, which were all generally supportive. However, the commenters raised several issues regarding beneficiaries covered by this rulemaking, specific services provided, definitions included in the proposed rule, and provision of

health care through non-VA care (care in the community). We respond to these comments below and adopt as final the proposed rule, without change.

Scope of the rulemaking

One commenter stated that children of Vietnam veterans who have spina bifida may have children of their own, and VA should also provide care to grandchildren of Vietnam veterans who have spina bifida. The commenter stated that according to the US National Library of Medicine, spina bifida is likely caused by the interaction of multiple genetic and environmental factors, and that genetic changes in individuals with spina bifida may increase the risk of neural tube defects in the subsequent generation. The commenter stated that if a child with spina bifida can establish that the grandfather was exposed to herbicides during the Vietnam War, that child should also be covered.

Another commenter stated that children of Air Force active duty servicemembers and reservists who were exposed to Agent Orange while flying C-123 aircraft both during the Vietnam War and the post-war period should also be covered. The commenter noted that these servicemembers flew out of air bases in Thailand and Clark Air Base in the Philippine Islands, and some of the airplanes potentially contaminated by Agent Orange remained in service after the war.

In response to the first comment, VA does not have statutory authority to provide health care to grandchildren of Vietnam veterans who may have spina bifida. VA's authority to provide health care to children with spina bifida or other covered birth defects is limited by statute. A "child" covered under this statute is defined at 38 U.S.C. 1831(1) as an individual, regardless of age or marital status, who is the natural child of a

Vietnam veteran, and was conceived after the date on which that veteran first entered the Republic of Vietnam during the Vietnam era; or, is the natural child of a veteran of covered service in Korea (as determined for purposes of 38 U.S.C. 1821), and was conceived after the date on which that veteran first entered service described in 38 U.S.C. 1821(c).

With respect to the second comment, VA also does not have the authority to extend benefits under 38 U.S.C. Chapter 18 to children of veterans who did not serve in the Republic of Vietnam during the Vietnam era or who did not have certain service in Korea. "Vietnam veteran" is defined at 38 U.S.C. 1831(2) to mean an individual who performed active military, naval, or air service in the Republic of Vietnam during the Vietnam era, without regard to the characterization of that individual's service. The "Vietnam era" is defined at 38 U.S.C. 1831(3) as ending on May 7, 1975. A veteran of covered service in Korea is any individual, without regard to the characterization of that individual's service, who served in the active military, naval, or air service in or near the Korean demilitarized zone (DMZ), as determined by the Secretary in consultation with the Secretary of Defense, during the period beginning on September 1, 1967, and ending on August 31, 1971; and is determined by VA, in consultation with the Department of Defense, to have been exposed to an herbicide agent during such service in or near the Korean demilitarized zone. 38 U.S.C. 1821(c). To the extent a veteran who flew in a C-123 is also a veteran with covered service defined in 38 U.S.C. 1831(2) and has a child covered by 38 U.S.C. 1831(1), however, the child would be eligible for benefits under Chapter 18.

In further response to the comment regarding reservists and servicemembers who flew in C-123 aircraft, we note that VA does have authority in certain other circumstances to extend benefits to veterans who did not serve in those defined areas or time periods, but may have been exposed to Agent Orange. This authority is unrelated to benefits furnished to eligible children under 38 U.S.C. Chapter 18 but we briefly discuss it here because a recent VA rulemaking is relevant to the second public comment. On June 19, 2015, VA published an interim final rule (80 FR 35248) extending the presumption of herbicide exposure and presumption of service connection to individuals who performed service in the Air Force or Air Force Reserve under circumstances in which the individual concerned regularly and repeatedly operated, maintained, or served onboard C-123 aircraft known to have been used to spray an herbicide agent during the Vietnam era. The June 2015 interim final rule thus covers servicemembers who were potentially exposed to Agent Orange during periods after the end of the Vietnam War, and in regions outside of Vietnam. VA determined that the presumption of service connection should be extended to these servicemembers based on a January 2015 report from the National Academies of Sciences, Engineering, and Medicine's Institute of Medicine (IOM) titled "Post-Vietnam Dioxin Exposure in Agent Orange-Contaminated C-123 Aircraft." In that report the IOM noted that between 1972 and 1982, approximately 1,500 to 2,100 U.S. Air Force Reserve personnel trained and worked on C-123 aircraft that previously had been used to spray herbicides, including Agent Orange, during Operation Ranch Hand. Based on a review of the evidence, IOM concluded that it was plausible that Air Force reservists flying C-123 aircraft used in Operation Ranch Hand were exposed to Agent Orange.

We make no changes based on these comments.

Definitions

One commenter asked whether the proposed addition of day health care to the list of health care services would require the beneficiary to transfer to a group home. In the proposed rule we defined day health care to mean a therapeutic program prescribed by an approved health care provider that provides necessary medical services, rehabilitation, therapeutic activities, socialization, nutrition, and transportation services in a congregate setting. Day health care services contemplated under this proposal are non-residential and equivalent to adult day health care provided to disabled veterans under 38 CFR 17.111(c)(1). These would not require the beneficiary to relocate to a group home. The essential features are the therapeutic focus of the day health care services and provision of these services in a congregate setting. The addition of day health care to the list of covered health care services augments rather than contracts the options available. Day health care is an alternative care setting that can allow some beneficiaries who require long term care services to remain in their homes rather than be institutionalized in a nursing home. Such beneficiaries typically require support for some, but not all, Activities of Daily Living (ADLs), such as bathing, dressing or feeding. In many cases, a family member may provide the beneficiary with much of their care, but require additional support for some ADLs. By filling these gaps, day health care can allow these beneficiaries to remain in their homes and communities for additional months or even years. Day health care programs can help caregivers to meet their

other professional and family obligations, or provide a well-deserved respite, while their loved ones are participating in the program.

Two commenters urged VA to allow payment for homemakers and home health aides to shop for groceries outside of the home. Homemaker and home health aide (H/HHA) services are health-related services. VA provides health-related services, including H/HHA services, to veterans under 38 U.S.C. 1720C. We proposed to provide H/HHA services to spina bifida beneficiaries similar to that provided to veterans, to the extent allowed by law. Under 38 U.S.C. 1720C, VA may provide H/HHA to veterans in “noninstitutional settings.” This includes services performed outside the home, such as grocery shopping and escorting the veteran to necessary appointments. VA may not provide such services to beneficiaries under the Spina Bifida Health Care Benefits Program, health-related services for spina bifida beneficiaries are included as a component of home care. Home care is defined at 38 U.S.C. 1803(c)(3) as outpatient care, habilitative and rehabilitative care, preventive health services, and health-related services furnished to an individual in the individual's home or other place of residence. This definition specifically limits the provision of health-related services under 38 U.S.C. 1803 to those services furnished within the home or other place of residence. Grocery shopping, which is an H/HHA type of health-related service performed outside the home or other place of residence, cannot be provided due to this statutory restriction that applies to the Spina Bifida Health Care Benefits Program, but not to VA’s authorities to provide care to veterans.

One commenter supported the proposed rule, but urged us to amend the definition of “other place of residence.” As noted above, home care, including health-

related services such as H/HHa services, is provided in the individual's home or other place of residence. We proposed to define other place of residence to include an assisted living facility or residential group home. Assisted living facilities and residential group homes are appropriate for individuals who do not require the level of care provided in a nursing home, and VA believes that providing home care in assisted living facilities and residential group homes will allow individuals to retain a greater level of independence and quality of life, and delay or prevent any need for nursing home care. While VA may provide services to an individual residing in an assisted living facility or residential group home, we do not have the statutory authority to pay for placement in such facility. The types of alternatives to home care that VA may provide under 38 U.S.C. 1803 are nursing home care, hospital care, and respite care. The commenter suggested amending the definition of “other place of residence” to state that “placement in such facility or home is covered to the extent that the facility or home provides covered care or services.” The commenter stated that this would clarify that VA can provide for placement in an assisted living facility or residential group home to the extent that such location provides aspects of care or services covered under 38 U.S.C. 1803. We do not agree. Payment for placement in an assisted living facility or residential group home is distinctly different than providing for care and services rendered in such facility. While VA cannot do the former, we may do the latter to the extent allowed by law. VA believes that the suggested language would lead to confusion as it implies that VA can cover, to some extent, placement in an assisted living facility or residential group home.

One commenter asked for clarification of what long-term care means as that term applies to H/HHA services. Specifically, the commenter asked whether a spina bifida beneficiary would be entitled to receive H/HHA services around the clock and indefinitely. One commenter asked whether there would be a limit on the number of hours of H/HHA services that a beneficiary may receive. As noted above, H/HHA services provided to spina bifida beneficiaries are similar to that provided to veterans, to the extent allowed by law. Under 38 U.S.C. 1720C, VA is authorized to provide veterans with health-related services in a non-institutional setting. The total cost of providing such services or in-kind assistance to any veteran in any fiscal year may not exceed 65 percent of the cost that would have been incurred by VA during that fiscal year if the veteran had been furnished, instead, nursing home care under 38 U.S.C. 1710. See 38 U.S.C. 1720C(d). The same limitation is applied currently to H/HHA services provided to spina bifida beneficiaries and will continue to apply under this rule. Consistent with this limitation, H/HHA services will be provided to spina bifida beneficiaries if medically necessary.

The commenter also requested clarification on what type of health care provider must prescribe H/HHA services. These services must be prescribed by an approved health care provider. Under § 17.900, “approved health care provider” means a health care provider currently approved by the Center for Medicare and Medicaid Services (CMS), Department of Defense TRICARE Program, Civilian Health and Medical Program of the Department of Veterans Affairs (CHAMPVA), Joint Commission, or currently approved for providing health care under a license or certificate issued by a governmental entity with jurisdiction.

The commenter also raised several procedural issues that are beyond the scope of this rulemaking.

We make no changes based on these comments.

Miscellaneous

One commenter stated that health care should be provided directly by VA health care providers rather than through care in the community. However, children with covered birth defects or spina bifida require specialty care that may not be available in a VA medical center, and requiring the beneficiary to commute to a VA medical facility could impose an undue burden on the caregiver. Here, care in the community ensures that the beneficiary receives necessary specialty medical care in a timely manner, and eliminates the need to travel to the nearest VA medical center to obtain that care.

Based on the rationale set forth in the preamble to the proposed rule and in this preamble, VA is adopting the proposed rule as a final rule, with no changes.

Effect of Rulemaking

Title 38 of the Code of Federal Regulations, as revised by this final rulemaking, represents VA's implementation of its legal authority on this subject. Other than future amendments to this regulation or governing statutes, no contrary guidance or procedures are authorized. All existing or subsequent VA guidance must be read to conform with this rulemaking if possible or, if not possible, such guidance is superseded by this rulemaking.

Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3507) requires that VA consider the impact of paperwork and other information collection burdens imposed on the public. Under 44 U.S.C. 3507(a), an agency may not collect or sponsor the collection of information, nor may it impose an information collection requirement unless it displays a currently valid Office of Management and Budget (OMB) control number. See also 5 CFR 1320.8(b)(2)(vi).

This final rule will impose the following amended information collection requirements. Preauthorization from VA under 38 CFR 17.902(a) is required for certain services or benefits under §§ 17.900 through 17.905. Information collection under this rule is approved under OMB control number 2900-0219. VA is making a minor modification to this information collection by requiring preauthorization for mental health services only for outpatient mental health services, and only when those services are provided in excess of 23 visits in a calendar year. VA also adds day health care provided as outpatient care and homemaker services to the list of services or benefits that must receive preauthorization. VA anticipates that the decrease in the number of beneficiaries that must request preauthorization for mental health services will be offset by the number of beneficiaries that will request preauthorization for day health care. Therefore, we believe that there will be little, if any, change in the total burden hours as a result of this modification. As required by the 44 U.S.C. 3507(d), VA submitted these information collection amendments to OMB for its review, and the information collection is pending OMB approval. Notice of OMB approval for this information collection will be published in a future Federal Register document.

Regulatory Flexibility Act

The Secretary hereby certifies that this final rule will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601-612. This final rule will directly affect only individuals and will not directly affect small entities. Therefore, pursuant to 5 U.S.C. 605(b), this rulemaking is exempt from the initial and final regulatory flexibility analysis requirements of 5 U.S.C. 603 and 604.

Executive Orders 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and other advantages; distributive impacts; and equity). Executive Order 13563 (Improving Regulation and Regulatory Review) emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. Executive Order 12866 (Regulatory Planning and Review) defines a “significant regulatory action,” requiring review by the Office of Management and Budget (OMB), unless OMB waives such review, as “any regulatory action that is likely to result in a rule that may: (1) Have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) Create a serious

inconsistency or otherwise interfere with an action taken or planned by another agency; (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order."

The economic, interagency, budgetary, legal, and policy implications of this final rule have been examined, and it has been determined not to be a significant regulatory action under Executive Order 12866. VA's impact analysis can be found as a supporting document at <http://www.regulations.gov>, usually within 48 hours after the rulemaking document is published. Additionally, a copy of the rulemaking and its impact analysis are available on VA's Web site at <http://www.va.gov/orpm/>, by following the link for "VA Regulations Published From FY 2004 Through Fiscal Year to Date."

Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more (adjusted annually for inflation) in any one year. This final rule will have no such effect on State, local, and tribal governments, or on the private sector.

Catalog of Federal Domestic Assistance

There are no Catalog of Federal Domestic Assistance numbers and titles for the programs affected by this document.

Signing Authority

The Secretary of Veterans Affairs, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs. Robert D. Snyder, Chief of Staff, Department of Veterans Affairs, approved this document on March 31, 2016, for publication.

List of Subjects in 38 CFR Part 17

Administrative practice and procedure, Alcohol abuse, Alcoholism, Claims, Day care, Dental health, Drug abuse, Government contracts, Grant programs-health, Grant programs-veterans, Health care, Health facilities, Health professions, Health records, Homeless, Medical and dental schools, Medical devices, Medical research, Mental health programs, Nursing homes, Reporting and recordkeeping requirements, Travel and transportation expenses, Veterans.

Dated: April 1, 2016

William F. Russo
Director,
Office of Regulation Policy & Management,
Office of the General Counsel,
Department of Veterans Affairs.

For the reasons set out in the preamble, the Department of Veterans Affairs amends 38 CFR part 17 as follows:

PART 17 – MEDICAL

1. The authority citation for part 17 continues to read as follows:

AUTHORITY: 38 U.S.C. 501, and as noted in specific sections.

2. Amend § 17.900 by:

- a. In the definition of “Approved health care provider” removing “Joint Commission on Accreditation of Health Care Organizations (JCAHO)” from the first sentence and adding, in its place, “The Joint Commission”.

- b. Adding in alphabetical order a definition of "Day health care";

- c. In the definition of “Health care” adding “long-term care,” to the first sentence immediately after “hospital care,”.

- d. Adding in alphabetical order definitions of "Health-related services", "Home health aide services", "Homemaker services", "Long-term care", and "Other place of residence";

- e. In the definition of "Outpatient care" adding "day health care and" immediately after the word "including"; and

f. Revising the definition of "Respite care".

The additions and revision read as follows:

§ 17.900 Definitions.

* * * * *

Day health care means a therapeutic program prescribed by an approved health care provider that provides necessary medical services, rehabilitation, therapeutic activities, socialization, nutrition, and transportation services in a congregate setting. Day health care may be provided as a component of outpatient care or respite care.

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Health-related services means homemaker or home health aide services furnished in the individual's home or other place of residence to the extent that those services provide assistance with Activities of Daily Living and Instrumental Activities of Daily Living that have therapeutic value.

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Home health aide services is a component of health-related services providing personal care and related support services to an individual in the home or other place of residence. Home health aide services may include assistance with Activities of Daily Living such as: Bathing; toileting; eating; dressing; aid in ambulating or transfers; active and passive exercises; assistance with medical equipment; and routine health monitoring. Home health aide services must be provided according to the individual's written plan of care and must be prescribed by an approved health care provider.

Homemaker services is a component of health-related services encompassing certain activities that help to maintain a safe, healthy environment for an individual in the home or other place of residence. Such services contribute to the prevention, delay, or reduction of risk of harm or hospital, nursing home, or other institutional care. Homemaker services include assistance with personal care; home management; completion of simple household tasks; nutrition, including menu planning and meal preparation; consumer education; and hygiene education. Homemaker services may include assistance with Instrumental Activities of Daily Living, such as: Light housekeeping; laundering; meal preparation; necessary services to maintain a safe and sanitary environment in the areas of the home used by the individual; and services essential to the comfort and cleanliness of the individual and ensuring individual safety. Homemaker services must be provided according to the individual's written plan of care and must be prescribed by an approved health care provider.

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Long-term care means home care, nursing home care, and respite care.

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Other place of residence includes an assisted living facility or residential group home.

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Respite care means care, including day health care, furnished by an approved health care provider on an intermittent basis for a limited period to an individual who resides primarily in a private residence when such care will help the individual continue residing in such private residence.

* * * * *

3. Amend § 17.902 by:

- a. Revising the first three sentences of paragraph (a) introductory text; and
- b. At the end of the section, removing "2900-0578" from the notice of the Office of Management and Budget control number and adding, in its place, "2900-0219".

The revisions read as follows:

§ 17.902 Preauthorization.

(a) Preauthorization from VA is required for the following services or benefits under §§ 17.900 through 17.905: Rental or purchase of durable medical equipment with

a total rental or purchase price in excess of \$300, respectively; day health care provided as outpatient care; dental services; homemaker services; outpatient mental health services in excess of 23 visits in a calendar year; substance abuse treatment; training; transplantation services; and travel (other than mileage at the General Services Administration rate for privately owned automobiles). Authorization will only be given in spina bifida cases where it is demonstrated that the care is medically necessary. In cases of other covered birth defects, authorization will only be given where it is demonstrated that the care is medically necessary and related to the covered birth defects. * * *

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4. Amend § 17.903 by:

- a. In paragraph (a)(1), adding a second sentence; and
- b. At the end of the section, removing "2900-0578" from the notice of the Office of Management and Budget control number and adding, in its place, "2900-0219".

The addition reads as follows:

§ 17.903 Payme

(a)(1) * * * For those services or benefits covered by §§ 17.900 through 17.905 but not covered by CHAMPVA we will use payment methodologies the same or similar to those used for equivalent services or benefits provided to veterans.

* * * * *

§ 17.904 [Amended]

5. Amend § 17.904 by, at the end of the section, removing "2900-0578" from the notice of the Office of Management and Budget control number and adding, in its place, "2900-0219".

[FR Doc. 2016-07897 Filed: 4/5/2016 8:45 am; Publication Date: 4/6/2016]